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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/610,313	07/05/2000	Susan Barnett	PP01631.101	4221

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EXAMINER
WHITEMAN, BRIAN A

ART UNIT	PAPER NUMBER
1635	

DATE MAILED: 11/06/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action	Application No. 09/610,313	Applicant(s) BARNETT ET AL.	
	Examiner Brian Whiteman	Art Unit 1635	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 23 October 2002 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

a) ☒ The period for reply expires *1* months from the mailing date of the final rejection.

b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on _____. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.

2. ☐ The proposed amendment(s) will not be entered because:

   (a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);

   (b) ☐ they raise the issue of new matter (see Note below);

   (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or

   (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: _____.

3. ☐ Applicant's reply has overcome the following rejection(s): _____.

4. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).

5. ☒ The a)☐ affidavit, b)☐ exhibit, or c)☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: *See Continuation Sheet*.

6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.

7. ☒ For purposes of Appeal, the proposed amendment(s) a)☐ will not be entered or b)☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

   The status of the claim(s) is (or will be) as follows:

   Claim(s) allowed: *48,50 and 51*.

   Claim(s) objected to: _____.

   Claim(s) rejected: *1-40 and 42-47*.

   Claim(s) withdrawn from consideration: _____.

8. ☒ The proposed drawing correction filed on *23 October 2002* is a)☐ approved or b)☒ disapproved by the Examiner.

9. ☐ Note the attached Information Disclosure Statement(s)(PTO-1449) Paper No(s). _____.

10. ☒ Other: *See Continuation Sheet*

Continuation of 5. does NOT place the application in condition for allowance because: applicants' traversal is not found persuasive for one skilled in the art to make and/or use the full scope of the claimed invention because in view of the unpredictability for one skilled in the art to make and/or use an expression cassettes comprising a nucleotide sequences having at least 90% sequence identity to the sequence presented in SEQ ID NOs: 30-32 and in view of the art of record concerning the unpredictability of making and/or using a method of immunization and the lack of guidance provided by the as-filed specification, it would take one skilled in the art an undue amount of experimentation to make and/or use the full scope of the claimed invention. More specifically, the as-filed specification and/or applicants' traversal and/or Declaration under 1.132 do not provide sufficient guidance and/or factual evidence for what amino acids of any of the sequence listed above may be changed while Pol polypeptide activity observed with SEQ ID NOs: 30, 31, or 32 is retained. Since the relationship of the sequence of a peptide and its tertiary structure (e.g. its activity) are not well understood and are not predictable (Ngo et al. The Protein Folding Problem and Tertiary Structure Prediction, 1994, Merz et al (ed.), Birkhauser, Boston, MA, pp. 433 and 492-495), it would require an undue amount of experimentation for one skilled in the art to arrive at other sequences that have at least 90% sequence identity to the Pol polypeptide encoded by SEQ ID NOs: 30-32 and to make and/or use an expression comprising sequences that have at least 90% sequence identity to the Pol polypeptide set forth in claim 1 in a method of generating an immune response to HIV Pol polypeptide (SEQ ID NOs: 30, 31, or 32).

The traversal and the as-filed specification do not provide any sufficient guidance and/or factual evidence to overcome the concerns set forth by the art of record for making an expression cassette comprising SEQ ID NO: 30, 31, or 32 and using the cassette in a method of immunization because of the reasons set forth in the enablement rejection. The traversal only asserts that the specification provides sufficient guidance for one skilled in the art to make and use the expression cassettes comprising SEQ ID NO: 30, 31, or 32 and that the applicants are not required to establish whether these immunological responses are protective or therapeutic. In view of the concerns cited above by the art of record for making and/or using a method of immunization of a subject and the lack of guidance provided by the specification, it would take one skilled in the art an undue amount of experimentation to reasonably extrapolate from generating an immune response in a subject to a method of immunization in a subject.

In addition, the court in Enzo 188 F.3d at 1374, 52 USPQ2d at 1138 states:

It is well settled that patent applications are not required to disclose every species encompassed by their claims, even in an unpredictable art. However, there must be sufficient disclosure, either through illustrative examples or terminology, to teach those of ordinary skill how to make and use the invention as broadly as it is claimed.
In re Vaeck, 947 F.2d 48, 496 & n.23. 30 USPQ2d 1438, 1445 &n23 (Fed. Cir. 1991)(citation omitted). Here, however, the teachings set forth in the specification provide no more than a "plan" or "invitation" for those of skill in the art to experiment...; they do not provide sufficient guidance or specificity as to how to execute that plan. See Fiers v. Revel. 984 F.2d.1164, 1171, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993); In re Wright, 999 F.2d...[1557], 1562, 27 USPQ2d...[1510], 1514. [footnote omitted].

On this record, it is apparent that the specification and the applicants' traversal
(See page 6 of traversal, which states, "a response may or may not be protective and/or therapeutic" and "the immune response generated by the claimed expression cassette may be protective") provide no more than a plan or invitation in view of the art of record exemplifying the unpredictability of using the claimed expression cassettes in a method of immunization, for those skilled in the art to experiment with the HIV cassettes so as to provide a protective or therapeutic effect as intended by the as-filed specification at the time the invention was made.
See also Genetech Inc. v. Novo Nordisk A/S, 108 F.3d 1361, 1366, 42, USPQ2d 1001, 1005 (Fed. Cir. 1997)
("Tossing out the mere germ of an idea does not constitute enabling disclosure. While every aspect of a generic claim certainly need not have been carried out by an inventor, or exemplified in the specification, reasonable detail must be provided in order to enable the public to understand and carry out the invention.")

In view of the art of record and the lack of guidance provided by the specification; the specification does not provide reasonable detail for what protocols are required for a therapeutic or protective effect using claimed cassettes.

Furthermore, the traversal is not found persuasive with regard to a method of immunization in a subject, because it is not apparent as how one skilled in the art reasonably extrapolates, without undue experimentation, from the scope of mammal to the full scope of the claimed invention that would generate a treatment (encompasses partial/complete protection) and/or prevention (total protection) in any subject against any subtype of HIV. Even if the specification contemplated that a clear improvement using the synthetic expression cassettes in an immunogenic composition has been prophetically displayed in mice, it is not apparent as to how the prophetic examples are reasonably extrapolated to the full scope of the claimed invention, encompassing any host (e.g., snake, bird, fish, monkey, human, etc.) particularly given that there is no immunization generation evidence showing that the prophetic examples are a general phenomenon, and given the doubts expressed in the art of record.

Continuation of 10. Other: The after final amendment will be entered, however it does not overcome the rejections of record in paper no. 12.

DAVE T. NGUYEN
PRIMARY EXAMINER